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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/848,185	05/03/2001	Jay M. Short	DIVER1280-11	6495

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EXAMINER

LOEB, BRONWEN

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 02/02/2002

7

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

09/848,185

Applicant(s)

SHORT ET AL.

Examiner

Bronwen M. Loeb

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) 7 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-6 and 8-26 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 May 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: .

DETAILED ACTION

Claims 1-26 are pending.

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. §121:
 - I. Claims 1-6 and 8-26, drawn to a method to enrich for DNA sequences using co-encapsulation and DNA hybridization, classified in class 435, subclass 6.
 - II. Claim 7, drawn to a method for screening for an agent that modulates activity of a target cell component using co-encapsulation of the agent and a recombinant cell, classified in class 435, subclass 4.
2. The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions comprise steps that are not required for and/or not present in the other method. Group I requires encapsulation and DNA hybridization. Group II requires screening for modulation of an activity by co-encapsulating a cell and an agent.
3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

4. During a telephone conversation with Lisa Haile on 25 January 2002 a provisional election was made without traverse to prosecute the invention of Group I, claims 1-6 and 8-26. Affirmation of this election must be made by applicant in replying to this Office action. Claim 7 is withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

It is noted that withdrawn claim 7 appears to be drawn to the invention elected in parent application 09/636,778.

Specification

6. The disclosure is objected to because of the following informalities: In the Abstract, the word "nucleic" is misspelled on line 3.

On p. 41 [0147] a "β" appears to be missing in four instances.

On p. 42 [0148] a "β" appears to be missing in three instances.

On p. 54 [0185] there is a reference to "Figure X" however there is no such figure provide. Also, there appears to be a typographical error in the phrase "which can the be decorated"; should it be "then"?

On p. 56 [0189] in the phrase "liquid grown culture", should it actually be "growth"?

On p. 57 [0197] line 2 the phrase "compounds can are utilized" is grammatically incorrect.

Appropriate correction is required.

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

Drawings

7. The drawings are objected to because in Figure 7, "fluor" is misspelled; Figure 14 states "from host" whereas the in the Brief Description of the Drawings, it appears that the correct phrase should be "the library"; and in Figure 15 "growth" is misspelled. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the second paragraph of 35 U.S.C. §112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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9. Claims 1-6 and 8-26 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague and indefinite in that it lacks a step that clearly relates back to the preamble.

Claim 2 recites the limitation "recovered target DNA" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim.

Claim 3 recites the limitation "the organisms" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim 5 recites the limitation "the expression library" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim 6 recites the limitation "the DNA population" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim.

Claim 9 is vague and indefinite in reciting "derived from". The number and nature of the derivative steps is unknown, therefore the metes and bounds of the claim cannot be established.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. §102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the

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treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or
(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

11. Claims 1-5, 8-18, 20 and 24-26 are rejected under 35 U.S.C. §102(e) as being anticipated by Thompson et al (USP 5,824,485).

Thompson et al teach a method for screening molecular diversity wherein the genetic material for the expression library is from a plurality of species of organisms, the libraries may be "biased" by pre-screening using DNA probes which hybridize to sequences of interest (such as enzymes), thereby enriching for the target DNA, and the pre-screening is undertaken using encapsulation. Once pre-screened, the positive clones are then screened as an expression library for the activity of interest. The organisms may be a mixture of known and/or unidentified organisms, including terrestrial microorganisms, marine microorganisms and environmental samples. Extremophile microorganisms taught include thermophiles and barophilic. Organisms may be uncultured. The target DNA may comprise gene clusters or operons, and may encode a complete or partial metabolic pathway. Encapsulation methods taught are gel microdrops, agarose and semi-solid matrices which are assumed to encompass beads. Vectors taught include plasmids, cosmids, phagemids, artificial chromosomes, viral vectors and bacteriophage. Host cells taught include bacterial, fungi, plants, insect cells and animal cells. Detectable markers may be fluorescent or colorigenic agents (such as green fluorescent protein), or an enzymatic substrate. Detection by FACS is taught. See entire document, especially col. 4, line 55-col. 5, line 65, col. 9, lines 49-65, col. 11,

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lines 33-48, col. 13, line 33-col. 14, line 60, col. 17, line 65-col. 24, line 4, col. 26, lines 56-66, col. 31, line 58-col. 32, line 56, col. 33, lines 1-57, col. 34, line 62- col. 35, line 19, col. 36, line 60-col. 38, line 20 and col. 56, lines 30-31.

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. §103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. §103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. §103(c) and potential 35 U.S.C. §§102(e), (f) or (g) prior art under 35 U.S.C. §103(a).

14. Claims 1-6, 8-20 and 24-26 are rejected under 35 U.S.C. §103(a) as being unpatentable over Thompson et al as applied to claims 1-5, 8-18, 20 and 24-26 above, and in view of Short (USP 5,958,672).

Thompson et al does not teach the steps recited in pending claim 6 or enzymes such as oxidoreductases, transferases, hydrolases, lyases, isomerases or ligases. At the time the invention was filed, the steps of pending claim 6, and the enzyme classes

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recited in claim 19, would have been obvious to one of ordinary skill in the art for the pre-screening taught by Thompson et al to enrich for desired target DNA in an expression library. One of ordinary skill in the art would have been motivated to use these steps in order to generate a library of the positives for subsequent screening for the desired activity. One of ordinary skill in the art would have been motivated to identify enzymes in these classes to possibly identify polyketide-related enzymes which might yield possibly therapeutic molecules. See for instance Short, col. 1, line 60-col. 2, line 46, col. 3, lines 30-53, and col. 7, lines 45-52.

Conclusion

Claims 1-6 and 8-26 are rejected. Claims 21-23 are free of prior art.

Certain papers related to this application may be submitted to Art Unit 1636 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone numbers for the Group are (703) 308-4242 and (703) 305-3014. NOTE: If Applicant does submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bronwen M. Loeb whose telephone number is (703) 605-1197. The examiner can normally be reached on Monday through Friday, from 10:00 AM to 6:30 PM. A phone message left at this number will be responded to as

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soon as possible (usually no later than the next business day after receipt by the examiner).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel, can be reached on (703) 305-1998.

Any inquiry of a general nature or relating to the status of this application should be directed to Tracey Johnson, Patent Analyst whose telephone number is (703) 305-2982.

Bronwen M. Loeb, Ph.D.
Patent Examiner
Art Unit 1636

January 28, 2002



REMY YUCEL, PH.D
PRIMARY EXAMINER